1. Election/Restriction

The Office has presented a Restriction Requirement in the application specifying the following allegedly separate and distinct inventions:

I. Claims 21-32 and 39, drawn to a pharmaceutical formulation for treating sexual dysfunction comprising dopamine receptor agonist.

II. Claims 33-38 and 40, drawn to a method of increasing sexual desire by administering a formulation comprising a dopamine receptor agonist.

In a response filed April 15, 2002, Applicants' representative Jeffrey King made an election without traverse to prosecute the invention of Group I, claims 21-32 and 39. The election is hereby affirmed. By this election, no representations are made concerning the merits of the Restriction Requirement with respect to the possible existence of multiple distinct inventions among the originally presented claims. By this election, claims 33-38 and 40 are withdrawn from further consideration as being drawn to a non-elected invention.

2. Claim Objection

Claim 39 was objected to because the parenthetical term "(tmax)" is redundant. Applicants have amended claims 23, 24, and 39 to remove the term "(tmax)" thus obviating the objection. Applicants therefore respectfully request that the objection be withdrawn.

3. Rejections Under 35 U.S.C. § 102

Claims 21-28 and 39 were rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Cicinelli et al (1996) in view of *American Hospital Formulary Service* (1988) and Heaton et al. (1995). This rejection is traversed in part and is further obviated by amendment.

As an initial consideration, the Office has cited multiple references under 35 U.S.C. § 102. Normally, only one reference is used in making a rejection under 35

U.S.C. § 102. However, a 35 U.S.C. § 102 rejection over multiple references has been held to be proper when the extra references are cited to: (a) Prove the primary reference contains an "enabled disclosure;" (b) Explain the meaning of a term used in the primary reference; or (c) Show that a characteristic not disclosed in the reference is inherent. See MPEP 2131.01. The Office has provided no reason related to enabling disclosure, term definition, or inherency to explain why multiple references have been cited. Therefore, each cited reference will be considered alone and in combination. Applicants assert that the cited references, alone or in combination, do not anticipate the claimed invention.

In claim construction, the claim must be read as a whole. The weight of the preamble has the import that the claim as a whole suggests for it. If the body of the claim references part of the preamble, the preamble is entitled to more weight as a claim limitation.

> "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 116566 (Fed. Cir. 1999).

Applicants claim, in part, a nasally administered pharmaceutical formulation for treating sexual dysfunction in a mammalian subject. The claimed formulation, as amended, delivers a therapeutic amount of an apomorphine compound to produce a therapeutic result in the subject within about 30 minutes or less. The "therapeutic result" in the subject is the treatment of sexual dysfunction. Cicinelli et al. reports a nasal spray for a dopamine agonist, bromocriptine, for therapeutic treatment of hyperprolactinemic women. The Office further cites *American Hospital Formulary Service* to confirm the statement in Cincinelli et al. that bromocriptine is a dopamine agonist. Cincinelli et al. in view of *American Hospital Formulary Service* do not teach or suggest a therapeutic treatment for sexual dysfunction by administration of apomorphine, a dopamine receptor agonist.

Heaton et al. teach oral administration of apomorphine for treatment of impotence. Heaton et al. do not teach or suggest a nasally administered pharmaceutical formulation for treating sexual dysfunction as claimed by Applicants.

Applicants assert that the claimed invention is novel with respect to Cincinelli et al. in view of *American Hospital Formulary Service* and Heaton et al. Without acceding to the Office's arguments, Applicants have amended the claims solely to advance prosecution of the pending claims to allowance. Applicants therefore respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-332-1380.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Date: November 5, 2002

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

21. (Amended) A nasally administered pharmaceutical formulation for treating sexual dysfunction in a mammalian subject comprising a therapeutically effective amount of an apomorphine compound [a dopamine receptor agonist] in a formulation for enhanced nasal delivery which yields enhanced nasal absorption of said apomorphine compound [dopamine receptor agonist] to produce a therapeutic result in said subject within about 30 minutes or less.

22. (Amended) The nasally administered pharmaceutical composition of Claim 21, wherein administration of said apomorphine compound [dopamine receptor agonist] in said formulation for enhanced nasal delivery yields enhanced nasal absorption of said apomorphine compound [dopamine receptor agonist] to produce a therapeutic result in said subject within about 15 minutes or less.

23. (Amended) A nasally administered pharmaceutical formulation for treating sexual dysfunction in a mammalian subject comprising a therapeutically effective amount of an apomorphine compound [a dopamine receptor agonist] in a formulation for enhanced nasal delivery which yields enhanced nasal absorption of said apomorphine compound [dopamine receptor agonist] resulting in a time to maximal plasma concentration [(tmax)] of said apomorphine compound [dopamine receptor agonist] in said subject of about 20 minutes or less.

24. (Amended) The nasally administered pharmaceutical composition of Claim 23, wherein administration of said apomorphine compound [dopamine receptor agonist] in said formulation for enhanced nasal delivery yields enhanced nasal absorption resulting in a time to maximal plasma concentration [(tmax)] of said apomorphine compound [dopamine receptor agonist] in said subject of about 15 minutes or less.

25. The nasally administered pharmaceutical composition of Claim 21, wherein said subject is a female.

26. The nasally administered pharmaceutical composition of Claim 23, wherein said subject is a female.

27. The nasally administered pharmaceutical composition of Claim 21, wherein said therapeutic response is selected from an improvement of sexual desire in a male or female subject, or amelioration of erectile dysfunction affecting an erectile tissue of a male or female subject.

28. The nasally administered pharmaceutical composition of Claim 23, wherein said sexual dysfunction is selected from reduced sexual desire in a male or female subject, or erectile dysfunction affecting an erectile tissue of a male or female subject.

29. (Amended) The nasally administered pharmaceutical composition of Claim 21, wherein said apomorphine compound [dopamine receptor agonist] is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

30. (Amended) The nasally administered pharmaceutical composition of Claim 23, wherein said apomorphine compound [dopamine receptor agonist] is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

31. (Amended) The nasally administered pharmaceutical composition of Claim 21, wherein said apomorphine compound [dopamine receptor agonist] is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

32. (Amended) The nasally administered pharmaceutical composition of Claim 23, wherein said apomorphine compound [dopamine receptor agonist] is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

39. (Amended) A nasally administered pharmaceutical formulation for treating difficulty in achieving or inability of achieving orgasm in a female mammalian subject comprising a therapeutically effective amount of an apomorphine compound [a dopamine receptor agonist] in a formulation for enhanced nasal delivery which yields enhanced nasal absorption of said apomorphine compound [dopamine receptor agonist] resulting in a time to maximal plasma concentration [(tmax)] of said dopamine receptor agonist in said subject of about 20 minutes or less.